OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

1/09/17

TO: Michael L. Goodis, Acting Director
Registration Division
Office of Pesticide Programs

FROM: Marion Johnson, Branch Chief
Minor Use and Emergency Response Branch
Registration Division
Office of Pesticide Programs

NOTE RE: Repeat Section 18 Specific Exemption Requests for the Use of Oxytetracycline and Streptomycin in Florida Citrus to Manage Citrus Greening Disease (also known as Huanglongbing (HLB)) (EE#s 17FL02 (oxytetracycline) and 17FL03 (streptomycin))

This is the second year that the Florida Department of Agriculture and Consumer Services (FDACS) has submitted a request for exemptions for oxytetracycline and streptomycin to manage HLB disease, caused by the bacteria *Candidatus* liberibacter asiaticus (*C*las). With EPA concurrence, FDACS authorized these uses to begin on March 4, 2016 under the provisions of crisis exemptions, and EPA subsequently authorized the uses under specific exemptions, which expired on December 31, 2016. **For further details, the August 15, 2016 memo for the 2016 exemptions is attached.**

FDACS indicated that citrus producers averaged two antimicrobial applications to approximately 84 percent of their citrus acreage. A grower survey indicated that the majority of the acreage treated received between two and six antimicrobial sprays. No adverse effects were reported. Use under the emergency exemptions is summarized in the following table, from March through September, 2016:

Product	Pounds product	Pounds a.i.
FireWall™ 50 WP (streptomycin)	231,761	115,881
FireLine™ 17 WP (oxytetracycline)	612,657	104,152
Mycoshield ® (oxytetracycline)	634,000	107,865

In evaluating the previous exemption requests, EPA reviewers noted the need for more definitive efficacy data for these materials, as well concerns for potential impact on antibiotic resistance development in environmental microbes resulting from exposure to the antibiotics from this increased agricultural use. Concern was particularly noted for potential risk of increased antibiotic resistance in bacteria of human health significance. The following information summarizes an update of ongoing research, presented in the 2017 submission from FDACS.

Efficacy Research: A September 13, 2016 report from AgriSource (registrant for Firewall (streptomycin) and Fireline (oxytetracycline) summarized efficacy data collected from the past two seasons (2014-15 and 2015-16). This research is a result of cooperation between AgriSource and the USDA-Agricultural Research Service (ARS) Horticultural Research Laboratory (USHRL) in Fort Pierce, FL. Data was collected from four commercial Florida citrus operations from August 2014 until September, 2016, from seven locations across FL, containing over 1,615 commercial trees. Efficacy was evaluated by measuring the following indicators of tree health, from treated versus untreated controls: increase in tree height; reductions in leaf drop, branch die-back, and fruit drop; and increase in fruit load. Overall, the information indicated improvements in all areas, with more significant results during the second season of treatments. The *C*Las bacteria has not been cultured successfully under laboratory conditions, so infection level was determined by quantifying DNA titers for *C*Las using polymerase chain reaction (PCR), from tree samples prior to treatment and after treatment. Significant reductions were observed in all varieties tested, ranging from 44% to 77%.

Nufarm, the registrant for Mycoshield (oxytetracycline) is also conducting efficacy studies but results were not available yet. FDACS indicates that additional efficacy data collection is ongoing with over 70 field trials set up for 2016/2017, and results will be presented when available.

Because of the limited data available under commercial field use, FDACS also stated that the Citrus Research and Development Foundation (CRDF) has initiated a process to provide growers with the tools to allow a comparative assessment on their farms as they use these products this season. A guidance document was distributed to the industry in early April which specifies a standard set of data to be collected by growers; this was included in the FDACS submission to EPA. Due to the seasonality of the data collections and the need for end of season harvest figures this information will not be available until sometime next year. For a group of voluntary participants CRDF is also providing more comprehensive support for collection of information across multiple use scenarios and cropping systems.

Antibiotic Resistance: Foliar and soil samples were collected prior to and following treatments. Testing will be conducted on these samples by the registrants, but data is not expected to be available until mid-2017. In their 2017 submission, FDACS provided EPA with the registrants' protocols for testing the samples. Additionally, the CRDF has drafted a protocol to be used if all 3 products are used in a coordinated program, which was recently provided to OPP for feedback. The protocols outline initial testing of the samples to isolate any microbial populations with resistance to oxytetracycline or streptomycin. Testing will then be conducted on any resistant isolates collected for cross-resistance against several other major antibiotics. These protocols have been circulated to OPP reviewers, and FDA, CDC, and USDA contacts. An interagency discussion is scheduled within the next week and the resulting feedback will be provided to FDACS and their cooperators.

FDACS stresses that the availability of multiple antimicrobial products is crucial at this time to counter the impacts of this disease. FDACS indicates that the industry continues to support ongoing research toward development of alternative treatments and management strategies, as well as resistant citrus varieties. However, the continued availability of the requested materials at this time give producers options to help combat the devastating effects of HLB while other management options are being explored and developed.

Progress Toward Registration: Submissions to EPA for registration of both oxytetracycline and streptomycin on citrus are currently under review within the Agency.

Based on the above, I am recommending that the attached actions be approved.